OVERVIEW

NATIONAL INSTITUTES OF HEALTH

January 1977

THE NATIONAL INSTITUTES OF HEALTH
AN OVERVIEW - JANUARY 1977

NIH TODAY

NIH As Part of the PHS. The NIH is one of six Federal agencies that make up the Public Health Service, which in turn, is one of the five "Principal Operating Components" of the Department of Health, Education, and Welfare. From this relationship with the PHS--an organization going back 180 years--the NIH has acquired a mixed personnel system (regular civil servants and uniformed service officers) and a common body of statutory authorities imbedded in the Public Health Service Act.

Distinguishing Characteristics. For NIH, these include:

1. A mission preeminently of research--the principal responsibility for conduct and support of biomedical research within the Federal Government. (NIH does not have regulatory authorities or responsibilities to provide health services.)

2. The organization of its programs and activities around major disease and health problems.

3. The maintenance of a vigorous in-house research core, as intellectual anchor for national grant and contract programs.

4. An insistence on scientific and program excellence as main objectives at all levels of NIH activity.

5. Maximum involvement of the national research community in assessments of the quality of science for which support is sought; also in the identification and development of national program goals, priorities and policies. (As part of NIH "peer review" processes, the "scientific merit" of all research support requests is assessed by knowledgeable non-Federal scientists organized into a series of discipline-oriented Study Sections; then "program relevance" is reviewed by appropriate National Advisory Councils--one for each Institute--made up of other non-Federal scientists and interested members of the public).

6. Close interaction with, and a critical role in support of academic science institutions, particularly the Nation's leading medical centers.

Mission. The NIH mission is research--research with an ultimate practical purpose. Specifically, through conduct and support of biomedical research, NIH seeks to advance the Nation's capabilities for the diagnosis, treatment and prevention of disease. To this end, it supports:

1. Free ranging inquiry aimed at broadening the knowledge base of biomedical science. (While the progress of biomedical science in the world has been extraordinary over the past two decades of increasing NIH activity, the knowledge base is still grossly inadequate for significant advance against many of the most pressing health problems).

2. The development and conduct of organized research activities aimed at practical solutions of specific disease or health problem.

3. The training of specialized manpower to provide for future research and teaching capability.

4. Acceleration of the effective flow of new knowledge from centers of academic medicine to the universe of health care.

While there are other Federal investors in health research--for example, NSF, DOD, NASA, VA, and other parts of the PHS--NIH funding runs about 70% of the Federal total. (Research by other PHS agencies is fairly easily differentiated from that of the NIH: For example, FDA's research component supports its regulatory mission; ADAMHA research, once a part of NIH,[1/] is focused upon mental health, drug abuse and alcoholism, and is directly associated with dominant service activities; etc.)

NIH Organizational Arrangements. What began in 1887 as a small, basic in-house laboratory--a part of the Staten Island Marine Hospital--has become a complex aggregate, with 11,000 employees organized into an Office of the Director and 18 major components, supporting national programs covering all disease and health problems of man except those allotted to ADAMHA. The main organizing principle has been

1/ADAMHA's intramural research on mental health is still located at NIH

disease category. There are eight National Institutes directed at specific disease problems with two of these (the National Cancer Institute and National Heart, Lung and Blood Institute) representing statutorily identified national priorities. There are also three Institutes with cross-cutting responsibilities: one for general medical sciences, one for child health and human development, and--most recently--one for aging research.

There are also six research or research support divisions; and finally, the National Library of Medicine, which is one of three components of the National Library System, and has communication responsibilities across the entire health spectrum.

All of the NIH Institutes, and most of the other major components have their own Congressional appropriations; and all exercise a national leadership role in respective program areas.

The typical NIH Institute [see attached chart] includes (in addition to its Director's office), an extramural program component, which is responsible for the award of roughly 80% of the Institute's resources in the form of research grants or contracts. There is also an intramural program component (much smaller in dollar but larger in personnel requirements) for direct laboratory and clinical research on the Institutes assigned problems. Two outside advisory groups provide informed overview of each Institute's activities: A National Advisory Council (referred to above) reviews programs and program priorities and must recommend grant awardsbefore they can be paid; a Board of Scientific

Counselors is responsible for assessing the quality and direction of the intramural program.

Program Growth. The distinctive research mission of the NIH, together with the principle of organizing by major disease or health problem, have contributed to other obvious characteristics of the NIH. First, to the dramatic but somewhat misleading growth in funding over the past twenty years[2/] and--tied to this--NIH's increasing visibility in the world beyond science.

NIH's main program growth came during the decade 1956-1965, with its appropriations growing roughly 14-fold. Doubtless, a part of this was due to the post-World War II adoption of large-scale patronage of science by the Federal Government. Certainly NIH program growth also was helped immeasurably by its possession of one of the few Federal health missions--real or potential--that was relatively non-controversial. Also contributing substantially was the structuring of NIH programs by disease category. This structuring makes immediately obvious the social purpose to be served by investment in particular program areas, greatly facilitating the task of health lobbyists and key supporters on Congressional appropriation committees seeking solution of disease problems through research.

The NIH Role. Some portion of the relatively high visibility

2/While NIH funding has grown about 40-fold over this 20 year period, there has been little real program growth in terms of "constant" dollars since 1966, except in the national priority areas of cancer and, to a lesser extent, cardiovascular research.

of NIH today relates to the following:

1. The principal location of NIH is on the 320 acre "campus" in suburban Bethesda, 3/ where approximately 8000 employees maintain several hundred laboratories, a 516-bed research hospital known as the Clinical Center, and the National Library of Medicine. These activities are visible evidence of national commitment to health research goals. In aggregate, they constitute the largest biomedical research enterprise in the world.

2. NIH success in supporting science excellence is reflected year by year in Nobel and other outstanding science awards. Four scientists in the NIH intramural program are Nobel laureates; since 1938, 61 other scientists have received similar awards for work supported by the NIH.

3. About 80% of current NIH appropriations are expended in 20,000 research awards of various kinds, going to more than 1100 institutions in every State of the Union and to a number of foreign countries.

4. Roughly half of NIH extramural funds go to medical schools, supporting about one-quarter of total medical school expenditures (excluding care) and 80% of their research effort. This concentration of resources in medical schools provides added assurance that practical solution of disease problems will receive appropriate priority in research activities; it also contributes to the effectiveness with which research

3/Roughly, 2500 other employees work at off-site locations, with relatively small enclaves in Rocky Mountain, Montana and Frederick, Maryland; and one entire Institute (for Environmental Health Sciences) located at the Research Triangle, North Carolina. Managers of the various NIH extramural programs represent the largest block of off-site employees. These are located in nearby rental buildings.

findings are applied in health care; and, as a useful bonus, contributes to the quality of medical education.

5. NIH currently provides 40% of national support for biomedical research from all sources, or 56% omitting research and development supported by industry.

CURRENT ISSUES. A number of important issues about NIH concern those who perform science and those who patronize it through public processes.

From the perspective of the research community, there are a number of lesser issues but one of over-riding importance; *how to assure that the capacity and effectiveness of the present research system is fully sustained in the future?*

For public patrons, probably two issues stand out: *how to bring the strengths of the research community to bear in improving the quality of care available within the health care system;* and, *how to assure appropriate public accountability for science programs now at the $2.5 billion level?*

Sustaining Research Funding. Twenty years of collaboration between the Government and the research community has brought into being a research network that has both great power and creativity, yet a high perishability. While there is no objective answer to the question, "How much research is enough", the determination of how much is needed to maintain present levels of effort is an easy calculation. Currently, scientists

do not urge significant enlargement of their research network, major program increases, or new national priorities. Rather they seek to sustain the current pace of advance--which promises steady progress against stubborn chronic diseases now dominating the health scene, and a fair chance for spectacular gains against particular diseases over the next decade. Scientists are convinced that down this path--with its promise of ultimate prevention of disease problems--lies the Nation's best hope of improving health levels and bringing health care costs under control.

This "steady-as-we-go" stance assumes protection from erosion by inflation. It also assumes that assignment of new responsibilities will be accompanied by add-on resources. This concept includes continuing adjustments in program priorities but regards as critical the protection of funds in three areas: support of free ranging, investigator-initiated research; for bringing into the community each year a small number of new researchers with new ideas; and for training the next generation of investigators. As viewed by researchers, the principal threats to these goals are: the continuing impact of inflation; increased competition for Federal resources generally; new self-imposed limits on Congressional appropriations; and the small fractions represented by "controllables" in PHS/DHEW budgets (NIH funds representing 19% of those "controllable").

For a longer term alternative to annual appropriation uncertainties, one possibility would be to tie research funding to a fixed percentage of total health expenditures. This wouldn't be unreasonable, though problems are foreseeable. During the period 1965 to 1975, while total health costs moved from $39 billion annually to approximately $120 billion, the proportion of dollars devoted to research declined from 4.8% to 3.9%. Various research spokesmen have suggested "pegging" research in roughly a 4 to 5% range. This would be in line with a fairly conservative pattern of research investment by industry. Further study of feasibilities is warranted.

Other Research Community Concerns. These include:

1. Continuing pressures by outside interest groups for new emphases in various categorical disease areas--often with little regard to scientific opportunity or added resource requirements. There is no obvious solution to this perennial and probably inevitable problem--sometimes referred to as the "disease-of-the-month" or "the Institute-of-the-year" syndrome.4/

2. Growing Congressional and public pressures to expand the NIH research mission into activities at the health research/health care interface or to direct health care and

4/The most dramatic expression of categorical pressures came in the 1970-71 effort to make NCI a separate agency. While NCI remains with NIH, the National Cancer Act of 1971 gives the Cancer program considerable independence and a number of unusual authorities.

regulation. These include a legislative concern that science be accountable for validation of new technologies arising from research and that cost and other impacts in health care be considered as well as efficacy. A substantial extension of research responsibilities appears reasonable. The principal problem is to find acceptable and cost-effective ways to do this with minimal risk to the basic NIH research mission (See discussion below).

3. Worries continue among many scientists that the "sunshine laws" damage sensitive peer review processes on which the integrity of research programs depend. The right of scientists to primacy in the development of their own ideas is also put at risk by new procedures. Some mutually acceptable "middle ground" has to be found. An increase in public members for review and advisory bodies would be a start.

4. There is a clear need to meet rising public demands that the use of human subjects in research investigations be subjected to severe new limits and conditions; and that new technology be assessed for ethical, legal, and other social implications. Much--though not all--of what is being urged seems reasonable; acceptable accomodation is being sought. (The risk seen here is that the research community may become so enmeshed in administrative laws and regulations that an inappropriate regulatory role will have been thrust upon it).

Health Research from the Public Perspective. The steeply rising cost of health care and disparities in quality and availability have convinced many that the total health system is in a state of severe dysfunction and also incapable of self-correction. Increased Federal leadership of other government and voluntary sectors seems needed. From the standpoint of some in Congress, the relative successes of NIH and the research community indicate a wider adaptation of their roles and responsibilities as a partial corrective.

The NIH has undergone two extensive reviews in the past year[5/] and has, in addition, been conducting a self-examination of its roles in relation to the health system. We believe the Agency must continue to avoid regulation and delivery of service. But research must take greater responsibility for validation and dissemination of the fruits of research. NIH will propose new formal systems for purposes of standard setting, for obtaining "technical consensus" and assisting the health "consumer" beyond traditional research roles.

The latter is expected to be a subject of oversight hearings during this legislative session and dealt with in parallel to renewal of authorizations.

The interface between Federal Agencies, and between them and private activities in health research and care, needs address.

5/President's Biomedical Research Panel (5th public review of accountability and state of biomedical research--last previous: Wooldridge); also the report "Investigation of the National Institutes of Health" by the House Interstate and Foreign Commerce Subcommittee on Health and Environment, August 1976.

PHS Agency missions and capabilities are not sufficiently defined or complementary to serve well the variety of Federal purposed throughout the spectrum of health activities. A resolution of Administration intent might serve to guide Congress in its attempt to re-define authorities and promote much more effective interactions in the coming year. Examples of unresolved issues include:

1. Where should "health services research" (on medical records, systems for delivery of care, on economic and fiducial issues related to health) be conducted?

2. At what point does NIH close down purportedly short-term "demonstration and control" activities, and which Agency carries them further into actual service?

3. If the NIH assumes broader validation responsibility for new knowledge coming from research (often involving costly clinical trials), how is the much larger problem of validating existing practice to be handled? Will it be possible to find add-on money for such activities? (Would a "skim" from medicare and for other third-party payors be a feasible way to handle this problem, since validation does strengthen cost and quality control?)

Accountability Issues. One possible way to deal with accountability issues--a number of them touched on above--would be to establish uniform time-and-dollar limits across all NIH programs, preferably for 4- or 5-year authorization periods. Then tie authorization renewals to formally mandated Wooldridge-

type reviews. While under such a plan, many NIH programs would lose their present exemption from time and dollar limits, the off-setting gains through new systematic and reasonably credible processes could make this worth while. This too, could be grist for congressional oversight hearings.

ACTION ITEMS FOR THE SECRETARY'S ATTENTION, EARLY 1977

Legislation:

1. Senator Kennedy's Health Subcommittee is planning quick, one-year extensions of expiring NIH program authorizations, and oversight hearings across main biomedical research issues. An "omnibus" bill to cover extensions and issues will be introduced by mid-February. (The NIH has been asked to provide technical assistance in drafting specifications for this bill. With the approval of the Secretary-designate, this is being done).

2. Legislative extensions will require Departmental policy decisions on: Research Training (particularly pre-doctoral training and institutional awards); National Cancer Act extension (how long? with or without existing unusual authorities?[6/]); the lapse or extension of special authorities in two areas: NHLBI research and Title X population research. Previously approved Departmental proposals include two for strengthening the role

6/ The NIH position favors extension. NCI/NIH cooperation has avoided potential difficulties.

of the Director, NIH: authorization of a Presidentially appointed advisory board for across-NIH review; and the provision of a "skim" of up to 1% of NIH appropriations to be used by the Director for unexpected program contingencies.

Appointment of new Director, NCI. This is one of two Presidential appointments at the NIH. The position has been vacant approximately 2 1/2 months.

Appointments to NIH Boards, Councils, Commissions. At recent count, there were approximately 70 vacancies for Secretarial appointment to these bodies. How many the current Secretary will have attended to isn't clear. NLM's Board of Regents is a special problem. These are Presidential appointments and require Senate confirmation. The Board is down to one member. Six nominations were made by the current administrator but there has been no Senate action. In order to avoid some of the inappropriate appointments made in recent years, the NIH is seeking a strengthened advisory role in selection of appointees, particularly those requiring scientific competence.

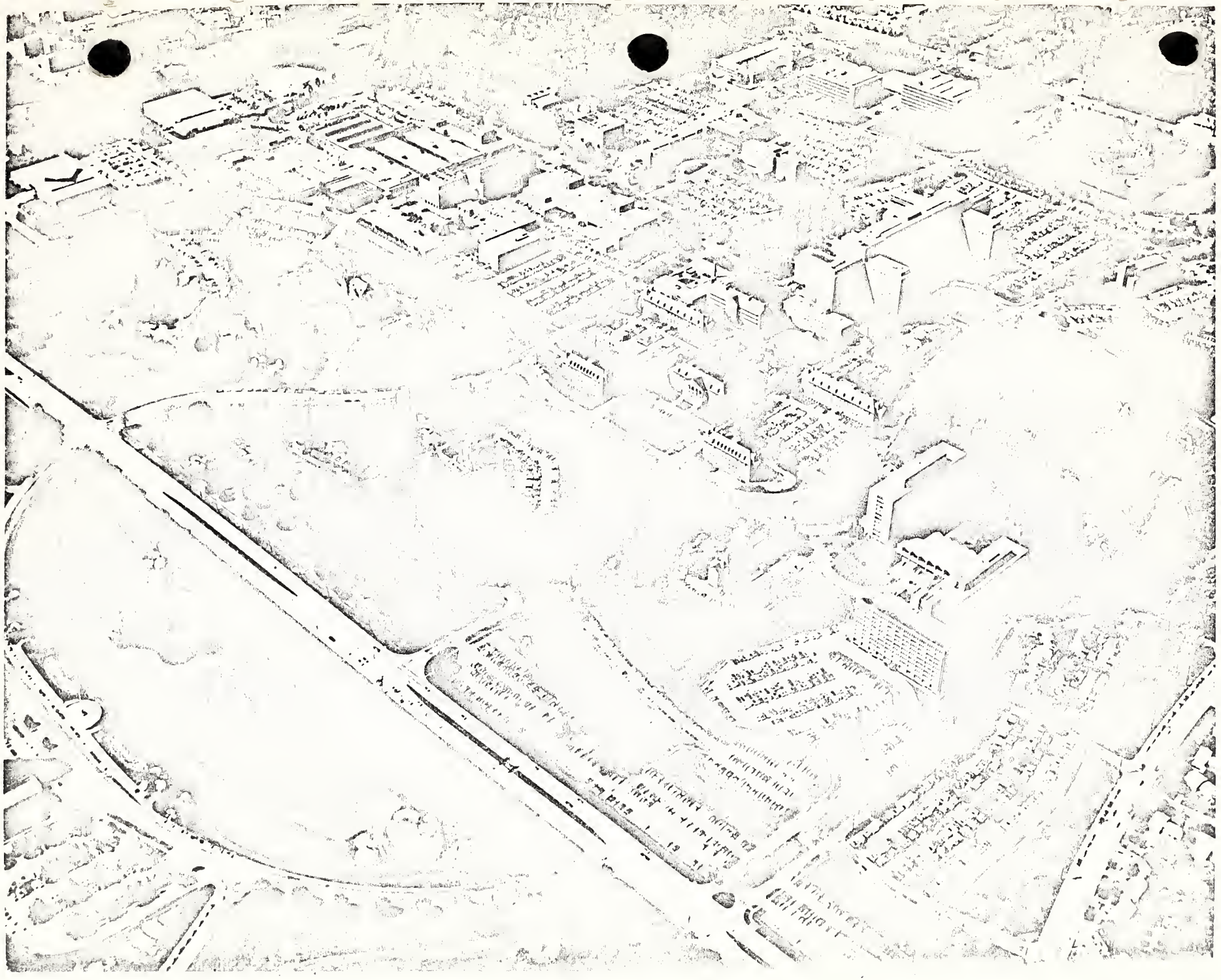
Reports. Two on or before early March:

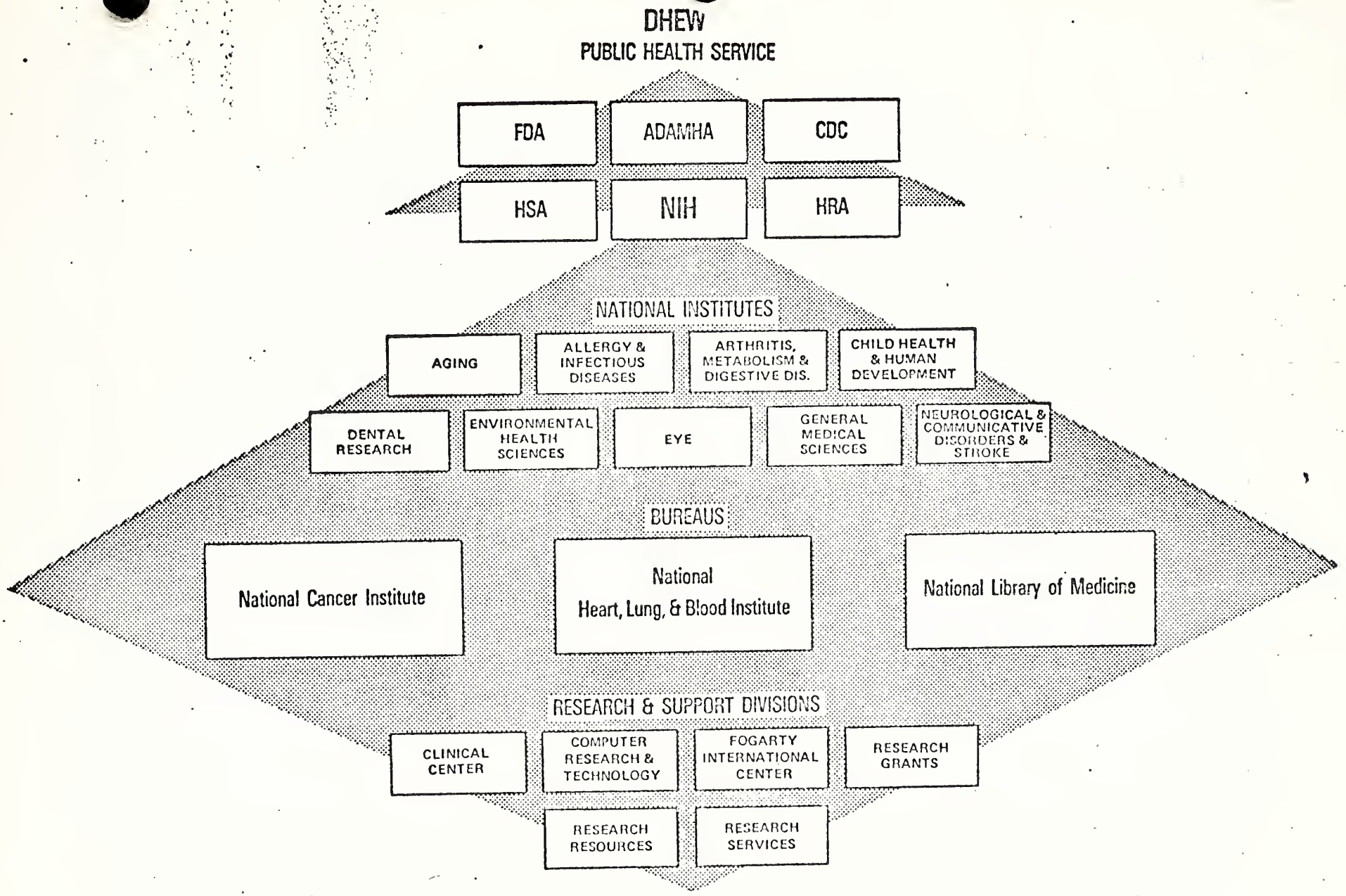
1. The Report of the Federal Interagency Committee on Recombinant DNA Research. This Committee (chaired by the Director, NIH) was convened by the Secretary at the President's

request. Its Report will have recommendations (for transmittal by the Secretary to the President) on legislative and possible Executive actions concerning the regulation of recombinant DNA research nationally.

2. The Secretary's Task Force on Compensation of Injured Research Subjects has completed an extended study and its report is now being cleared through NIH and the PHS.

Ambulatory Care Research Facility. As an increasingly important step in the modernization of its clinical research capabilities, the NIH is adding an Ambulatory Care Research Facility to its present Clinical Center. Plans have been approved and funding for the first construction increment was received in 1977 Appropriations. An early meeting with the new Departmental team is needed to review plans and projected costs.

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National Cancer Institute
National Heart, Lung, & Blood Institute
National Library of Medicine
RESEARCH & SUPPORT DIVISIONS
CLINICAL CENTER
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RESEARCH RESOURCES
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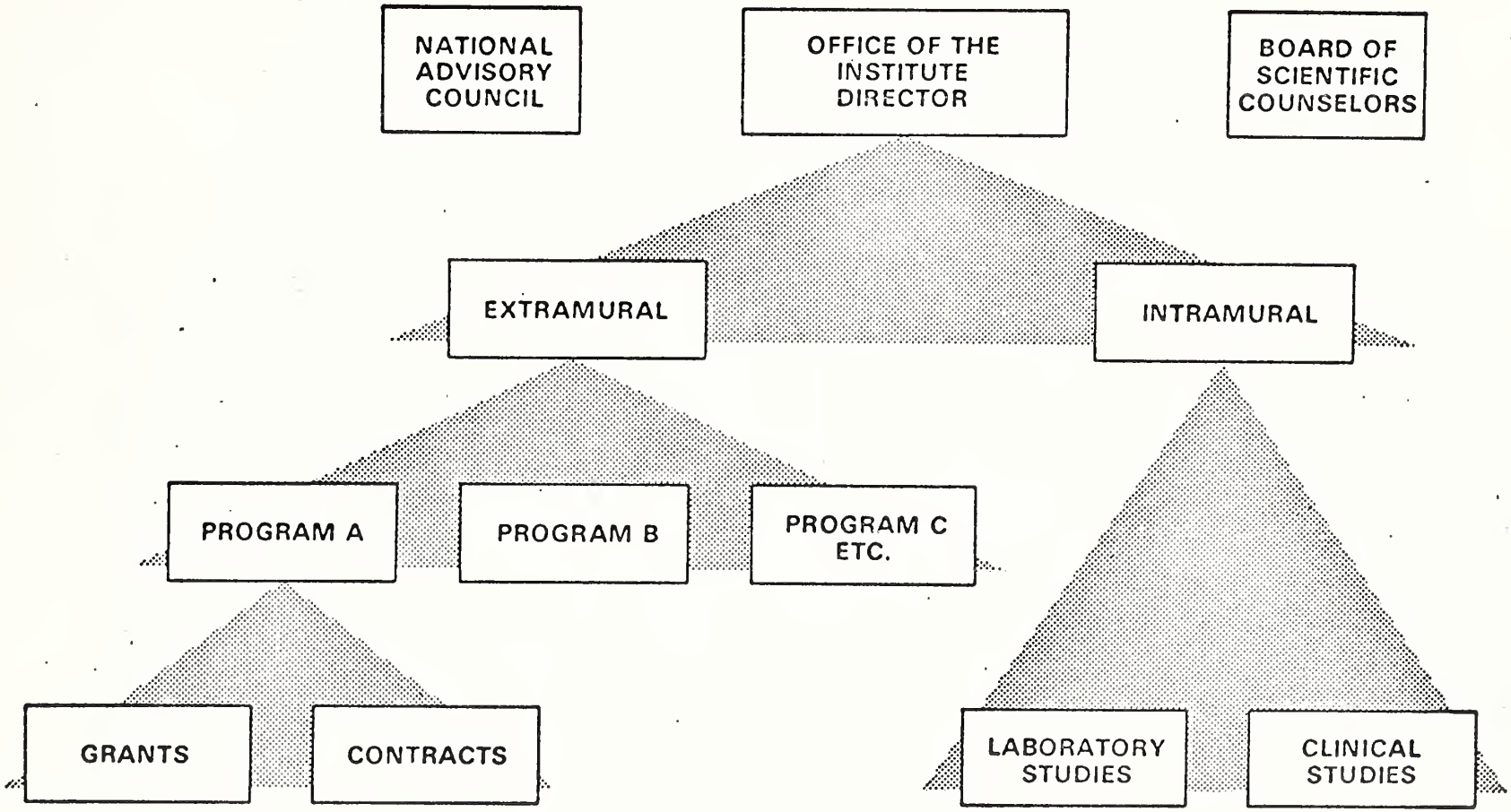
TYPICAL INSTITUTE OF NIH



NIH BRIEFING ISSUES 1977

The National Institutes of Health - An Overview - January 1977

Individual papers:

1. Categorical Disease Commissions and Boards
2. Notes for Possible Remarks by the Secretary at the NIH
3. NIH Advisory Groups
4. DHEW Ethical Advisory Board
5. The NIH Guidelines on Recombinant DNA Research
6. Study of Mission Boundaries of the NIH
7. Additional Topics on which to Brief the Secretary

NIH BRIEFING ISSUES 1977

1. CATEGORICAL DISEASE COMMISSIONS AND BOARDS

Issue: What should be the Administration position on the creation of disease-oriented Boards and Commissions? What can or should be done about existing Boards and Commissions?

NIH Recommended Position: In summary, the NIH recommendation is that the Administration--

(1) oppose the establishment of any new advisory bodies on categorical diseases. Any exceptions should be justified only on the basis of some extraordinary scientific opportunity in relation to a pressing societal need; and

(2) "live with" the currently established categorical disease-oriented Commissions and Boards.

Background: As indicated in the attached list, the past four years have been marked by Congressional establishment of six categorical disease commissions charged with responsibility for: surveying the state of knowledge on the cause, control, and prevention of the diseases with which they are concerned; formulating a long-range research plan; and reporting to the Congress and the Secretary on their findings and recommendations to advance a "national attack" on the respective diseases. Frequently they have been charged with reviewing services and public education needs as well. In the case of diabetes and arthritis, completion of the Commissions' work has been followed by statutory establishment of three-year Boards with program oversight responsibilities.

The recent Congressional willingness to establish Commissions and Boards in categorical disease areas can be attributed to several factors: the growing strength and sophistication of various advocacy groups and the present trend toward increased citizen participation in Government; the perception on the part of the public and the Congress that problems exist that are not amenable to normal administrative and scientific processes; and the concern of Congress that it be responsive to perceived needs. The Commissions and Boards have been viewed, with some justification, as less costly alternatives to establishing new institutes or to elaborate new legislative mandates such as those of NCI or NHLBI.

Benefits and Drawbacks of the Commissions and Boards: The NIH experience with Commissions has been mixed. It is clear that the highlighting of specific disease entities tends to create a stimulus to researchers in the field as well as to provide the various NIH Institutes with some valuable advice and an opportunity to re-evaluate ongoing programs and current research directions. Admittedly, however, these groups have been "thrust upon" the NIH at a time when the agency has been under severe fiscal and manpower constraints. Many of the recommendations of the Commissions are difficult--if not impossible--to implement in full within existing resource allocations. In addition, to provide a Commission with adequate staffing and support services, the NIH Institute "housing" a Commission often has been forced to divert considerable resources from ongoing programs to Commission operations. Costs of some Commissions are as high as $1.5 million for up to a two-year period. The Arthritis and Diabetes Boards have each been authorized to expend $300,000 a year for three years.

In addition, the usefulness of a particular Commission varies according to the disease entity in question, the individuals who comprise the membership, and the ability of the relevant NIH Institutes to be responsive administratively and programmatically to the desires and perceived needs of the Commission.

A Board represents a different set of problems than a Commission. It is unlike any other NIH advisory body, comparable only to the President's three-person Cancer Panel. The basic function of the two established Boards is to monitor Federal activities from the viewpoint of a single disease. They have been granted a public platform by the Congress and potentially wide latitude to blur the important distinction between giving advice and managing programs. We feel this kind of mandate could prove to be highly disruptive to the orderly planning and operation of many programs--not just those related to diabetes and arthritis, and will set a precedent for similar action in other disease areas.

A critical problem with both Boards and Commissions is that advocates' perceptions of the need for more research on a particular disease may be wholly out of step with actual research opportunity. While they were created in large measure from a sense of public urgency and from the perception that present research efforts were inadequate, the building up of relevant research fields and the necessary basic knowledge take time. The very establishment of Commissions and Boards tends to raise expectations which cannot be realized in the short run. These factors can combine to produce a counter-productive tension between the NIH and certain of the advocacy groups.

A related problem springs from the proliferation of these groups. Each one advocates increased resources and attention to its own cause regardless of other considerations. The advice may be helpful; the pressure for full implementation of each set of recommendations is antithetical to proper management, planning, and allocation of resources. Moreover, as the establishment of the Diabetes and Arthritis Advisory Boards indicates, once a Commission is established, the momentum to escalate activities is very difficult to slow down. Experience has also shown that, when one categorical disease-oriented group achieves legislative recognition, others are encouraged to demand equal treatment.

Special interest groups see few disadvantages in Commissions and Boards and may even band together, supporting one cause one year and a different one the next year.

Conclusion: For the present, it is recommended that the extant bodies run their present statutory courses without interference. The political costs of promoting categorical Commissions and Boards would be high and would tend to galvanize advocacy groups into positions of strong opposition to the Administration.

For the future, the convening of advisory groups of this nature should be on an ad hoc basis for a limited time. Their charge should be so framed as to preclude interference with sound operating procedures. This can be accomplished, as occasion warrants, by administrative action in cooperation with Congressional and other groups interested in a given problem. However, except in unusual circumstances, legislation creating

long-term or permanent categorical advisory Commissions and Boards should be vigorously opposed.

We firmly believe that increased attention by NIH staff to these advocacy groups and their concerns will considerably alleviate pressures to form Commissions and subsequent Boards. Administrative and programmatic responsiveness will go far to accomplish informally the purposes for which the Commissions and Boards were established: visibility for programs related to particular disease entities. Particularly since much of the research on categorical diseases for which there is pressure to form Commissions is carried out among several Institutes, more visible efforts by NIH staff to identify and coordinate such trans-institute activities can counter pressures and facilitate proper program planning.

Active Disease-Oriented Boards and Commissions, Legislative Authorization, and Status.

. Commission for the Control of Epilepsy and Its Consequences
  P.L. 94-63
  Will complete report Spring of 1977

. Commission for the Control of Huntington's Disease and Its Consequences
  P.L. 94-63
  Will complete report Summer of 1977

. National Commission on Digestive Diseases
  P.L. 94-562
  Chartered; expected to complete report Summer of 1978

. National Arthritis Advisory Board
  P.L. 94-562
  Chartered; has continuing responsibilities for oversight through September 30, 1980

. National Diabetes Advisory Board
  P.L. 94-562
  Chartered; has continuing responsibilities for oversight through September 30, 1980

Disease-Oriented Commissions that have Completed Their Reports Recently.

. National Commission on Multiple Sclerosis
  P.L. 92-563
  Report submitted February 1974

. National Commission on Diabetes
  P.L. 93-354
  Report submitted December 1975

. National Commission on Arthritis
  P.L. 93-640
  Report submitted April 1976

2. NOTES FOR POSSIBLE REMARKS BY THE SECRETARY AT THE NIH

Issue: What topics would it be appropriate for the Secretary to touch upon if he is able to make a visit to the NIH sometime in the near future?

NIH Suggestions:

The "de-politicization" of the NIH. Clarification, further extension of comments made at the January 26 press conference would be of great interest. [Selection processes for appointments to NIH advisory bodies are of keen interest both to scientists and science-administrators here].

* * * *

The NIH "peer review" system. Might indicate recognition of this NIH system as one of the best (if not the best) now in Government for allocating resources according to scientific quality and relevance, and for assuring integrity and impartiality of processes. [Might mention the need to make certain that system is fair, scrupulously avoids conflicts of interest, crony-ism or "old boy" networks, and has a good appeals process.]

* * * *

The excellence of the existing biomedical research system.

Comments along any of these lines would be welcomed by the NIH community:

o Recognition that what has been created here in Bethesda and across the Nation, through NIH research programs, is a world resource, unique for its size and quality.

* * * *

o [Possible "one-liner"]: "Now that Henry Kissinger is gone, this campus has regained its monopoly on Nobel laureates in the Federal service."

* * * *

o Recognition of the critical role played by NIH intramural laboratories and clinics here, in the Research Triangle, and other places; they are intellectual anchors for the much larger grant and contract programs that span the Nation.

* * * *

o Might note awareness that money has been appropriated to permit the first real modernization of the Clinical Center since 1950 (with addition of Ambulatory Care Research Facility)--with hint that quality of facilities should be maintained so that no excuse is provided for not sustaining excellence in the years to come.

* * * *

Maintaining the existing research system.

o If the existing research system is sustained, the Nation will be able to count on steady progress against disease and health problems.

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o What has been created to carry out biomedical research in America is perishable, and once dissipated, might be impossible to reassemble. Therefore, a very high priority must be given to maintaining the health and quality of the existing system.

* * * *

o [Possibly some caveats on difficulties of sustaining the system in the light of inflationary impacts, other health priorities, general economic difficulties?]

* * * *

o Recognition that key elements of the system include:

(1) A stable component of untargeted investigator-initiated research; wise choice of problems to be "targeted"

(2) Room in the system for entry each year of a reasonable increment of new investigators with new ideas

(3) Training the next generation of biomedical investigators, attracting and keeping a fair share of the intellectual cream of young college graduates.

* * * *

The importance of the NIH mission to Departmental responsibilities. Points that might be made here:

o Recognition that in research, with its promise of ultimate disease cures or prevention, has always lain the best long run hope for improved levels of health and reduction of health care costs.

* * * *

o Acknowledgement that the problems of the Department in the health area have become so vast--with public discontent fueled by runaway costs, lack of health care standards, wide disparities in quality and availability of care, enormous fiduciary complexities--that all health missions are placed under stress.

* * * * *

o [Question that might be posed]: Are there ways that the strengths of the research community can be brought to bear more effectively today in improving the quality and moderating the costs of health care?

* * * *

o Might note understanding that NIH is studying possible procedures through which the research community could assume a greater degree of responsibility for the quality and efficacy of new interventions passed from the laboratory to the health care system.

* * * *

o Note understanding that areas being studied for additional research community activity include: better identification of relevant research findings and more effective transfer to the health care community; assessing cost and other social impacts of new research techniques; recommendations on clinical practice as basis for standards setting; etc.

* * * *

o Recognize concerns of the research community that in accepting new responsibilities, one needs to keep NIH research out of direct health care or regulation.

* * * *

o Recognition that if major new responsibilities are assigned to the research system, compensating resources must also be provided.

Miscellaneous

o Pay. The long-awaited pay increase is much on the minds of high level scientists and clinicians. [Finesse this one?]

o [If the Secretary takes questions, he may count on some relating to equal opportunity for women and racial minorities].

3. NIH Advisory Groups

Issue: Two parts--

1. Should a strengthened advisory role be assigned to the NIH in the Secretarial appointment of scientific and public members to NIH advisory groups?

2. Should the NIH be given authority to establish or discontinue new technical advisory groups (with appropriate limitations) comparable to those now exercised by the National Cancer Institute through the National Cancer Act? Can paper work be reduced?

Recommended Position: Part 1

To minimize delays and avoid inappropriate appointments, the main responsibility for screening and selection of candidates for appointments to advisory groups should be assigned to the NIH. It would be most helpful if suggestions for membership sent to the Office of the Secretary are referred to NIH for consideration as early in the appointment process as possible. The recommendations of the Director, NIH concerning the suitability and competence of such candidates should ordinarily be determining in the selection process. The main purpose of review of nominations by HEW staff then would be to verify adherence to selection standards established by the Department. It is understood that in this strengthening of its role in the appointment process, the NIH accepts full responsibility for most careful adherence to all selection criteria (including geographic distribution, adequate representation of minorities and women and others specified in legislation or departmental policy).

Recommended Position: Part 2

Authority to establish or discontinue technical advisory groups should be delegated to the Director, NIH. Appropriate safeguards will be instituted by the NIH to ensure that these groups are established only when the requirement for them has been thoroughly substantiated (see discussion). Congress has given the Director of the National Cancer Institute authority to establish such advisory groups and it would be of great value to have this authority extended to the Director, NIH. Finally, a careful review of existing paper work requirements for chartering and rechartering is strongly recommended.

Discussion: Part 1

The PHS Act sets forth specific requirements for the appointment of members to NIH advisory groups. Scientific members must be recognized as outstanding leaders in their fields and considered to have broad interest in and understanding of the relationship of biomedical science to societal needs. Lay members must have a demonstrated interest and background relevant to the programs of the Institute and an appreciation of health needs of the public. In concert with existing administrative guidelines, it is NIH practice to select qualified candidates from the widest available pool, taking into account equitable representation of minorities and women, among other considerations.

A number of serious problems have been encountered in the current selection process. The absence of NIH control over the timing of appointment of members has resulted in delayed appointments and unfilled

vacancies, eroding the effectiveness of many advisory groups during the last several years.* Random substitutions for NIH nominations have been made without NIH knowledge, without adequate regard to selection criteria, and without consideration of the specific expertise to carry out statutory responsibilities of affected advisory groups. Liaison with responsible HEW staff has been inadequate for effective solution of problems.

Discussion: Part 2

In fulfilling its mission, the NIH uses panels of scientific experts to evaluate the scientific merits of biomedical research projects submitted for consideration of support. These groups perform the first level of review in the well-known and highly respected peer review system. For example, the NIH receives annually about 15,000 grant applications which are reviewed first by initial review groups and second by legally mandated national advisory councils or boards. This is apart from many hundreds of contract proposals and projects which are reviewed by technical evaluation groups and program advisory groups.

Over the past several years the workload of many of these groups has increased to levels which seriously threaten the quality of scientific recommendations. For example, the average workload of a typical NIH

* Roughly 70 past due appointments were made just before January 20. The Board of Regents of the National Library of Medicine (a Board requiring Presidential appointment and Senate confirmation for its members) has been the victim of most serious delays: it is down to one member (of ten authorized) and no new appointments have been made since 1974. While this Board requires Presidential appointment, much of the delay appears to have been in the Department.

study section has increased from a manageable level of 55 grant applications per meeting in 1969 to an average of over 90 applications per meeting in 1976. In 1973 the Administration terminated the authority for the NIH Research Manpower Training Programs and 49 training committees were abolished that had provided first level review of training grant and fellowship applications. With the passage of the National Research Service Awards Act in 1974 for the support of research manpower training, existing committees have had to assume the additional burden of reviewing applications received under the new program.

Coincident with these workload changes there has been strong pressure both in Congress and the Administration against the establishment of additional review groups. The NIH agrees with this general policy of establishing committees only when they are clearly essential. Accordingly, we would seek the creation of new committees only where this need was absolutely urgent through a significant upturn or shift in the workload. Such circumstances might include new legislative mandates, emerging science areas, major policy decisions in such areas as the review of ethics in human experimentation, the review of genetic research dangers, and so forth. On the other hand, we would be eager to discontinue committees when the need for them is past.

In addition to the escalating problem of workload, the situation has been further exaggerated by the inability of NIH to establish in a timely fashion an adequate number of new committees when needed. Under current Departmental procedures, it often takes six months or longer to

receive clearances for chartering new committees. A further complication is the detailed administrative process developed to comply with the legal requirement to file new charters every two years for all existing advisory groups. This process duplicates the procedures needed to establish new committees. Up to now the paper requirement for the establishment of a new committee usually exceeds one hundred pages of memoranda, attachments and copies. The requirement for rechartering (at two-year intervals) has been the same.

The authority sought is comparable to that afforded the Director of the National Cancer Institute in Section 410(a)(3) of the National Cancer Act of 1971.

4. DHEW Ethical Advisory Board

Issues: What is the Ethical Advisory Board? Why has it been chartered? Who are its members? What is its significance for Departmental activities? Who is responsible for staffing the Board and nominating its members?

Background: In 1974 Congress enacted the National Research Act (P.L. 93-348) which included two provisions directly related to the creation of a biomedical Ethical Advisory Board.

(1) It created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which in turn has recommended to the Secretary of HEW and to the Congress that a "national ethical review body" be established to review and approve projects presenting special problems in the areas of fetal research; research involving children, prisoners, the mentally disabled; and research relating to in vitro fertilization, psychosurgery, and behavior modification.

(2) It required the Secretary of HEW to establish a program to provide guidance with respect to ethical issues raised in connection with biomedical and behavioral research. This provision [Section 474(b) of the PHS Act] reflected recommendations of the Secretary's Study Group for the Protection of Human Subjects as well as public pressure to establish within the Department an ethical review mechanism which should complement the Department's scientific review system.

The NIH, in consultation with the Alcohol, Drug Abuse, and Mental Health Administration; the Food and Drug Administration; the Center for Disease Control; and the office of the Assistant Secretary for Health developed a charter for an Ethical Advisory Board and submitted it to the Assistant Secretary for Health on October 3, 1975. After discussions within the Department and the Office of Management and Budget, Secretary Mathews approved the Charter for the Ethical Advisory Board on December 27, 1976, and immediately delegated authority to the Assistant Secretary for Health to designate a chairman and to appoint members.

Charter of the Ethical Advisory Board: The Ethical Advisory Board shall advise the Department regarding biomedical and behavioral research activities covered by 45 CFR Part 46 (Regulations for the Protection of Human Subjects). The Board will also advise the Secretary, and other components of the Department with respect to ethical issues arising in connection with biomedical and behavioral research as required by Section 474( ) of the PHS Act.

The Board is also expected to review grant applications and contract proposals for a limited number of studies or training programs in the fields of biomedical ethics and the social, legal, and ethical impact of biomedical or behavioral research. Grants and contracts approved by the Board would be eligible for funding by the NIH.

Membership: The Board shall consist of 14 members, including the chairman. Members shall be competent to deal with ethical, legal, social,

and related biomedical issues. No more than seven members may be scientists, of whom four shall be biomedical scientists (including experts in pediatrics and gynecology) and three social or behavioral scientists (including an expert in psychiatry). The remainder shall be from other disciplines or representatives of the general public. The Board shall meet not less than three times per year and submit an annual report to the Secretary of HEW.

Recommendation:

Because the NIH has for many years been designated as the lead agency in the development of Departmental policy concerning protection of human subjects of biomedical and behavioral research, and because the NIH has been delegated responsibility for implementing Section 474(b) of the Public Health Service Act, it is recommended that the NIH provide administrative and staff support for the Ethical Advisory Board and that the Director, NIH, in consultation with other Public Health Service agencies, nominate persons for appointment as members by the Assistant Secretary for Health.

Attached for your consideration is a list of possible nominees to the Ethical Advisory Board, prepared after appropriate consultation as above.

Attachment

DHEW ETHICAL ADVISORY BOARD

Principal Listing

ETHICS AND MORALS

Richard McCormick, S.J., S.T.D.
Rose F. Kennedy Professor of
Christian Ethics
Kennedy Center for Bioethics
Georgetown University
3520 Prospect Street, N.W.
Washington, D. C. 20007

William B. Silverman
Rabbi, The Temple
Congregation B'nai Jehudah
712 East 69th Street
Kansas City, Missouri 64131

Frederick S. Carney
Professor of Christian Ethics
Southern Methodist University
Dallas, Texas 75222

LAW

Alexander M. Capron, LL.B.
Associate Professor of Law
University of Pennsylvania
Philadelphia, Pennsylvania 19174

Roger B. Dworkin, LL.B.
Associate Professor of Law
School of Law
Indiana University
Bloomington, Indiana 47401

PUBLIC REPRESENTATIVES

Geri Mack Joseph
5 Red Cedar Lane
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Mrs. Lorella L. Salazar
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P. O. Box 534
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BEHAVIORAL SCIENCES

Freedman, Daniel X.
Professor and Chairman
Department of Psychiatry
University of Chicago
Chicago, Illinois 60637

Bettye McDonald Caldwell
Professor of Education
Director, Center for Early
Development and Education
University of Arkansas
814 Sherman Street
Little Rock, Arkansas 72202

Ralph Kirkland Schwitzgebel, Ed.D., J.D.
Lecturer, Psychiatry
Laboratory of Community Psychiatry
Harvard Medical School
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BIOMEDICAL SCIENCES

Edward Quilligan, M.D.
Professor and Chairman
Department of Obstetrics and
Gynecology
School of Medicine
University of Southern California
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Dorothy Millicent Horstmann
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Pediatrics
Yale University Medical School
New Haven, Connecticut 06510

Robert F. Murray, Jr.
Professor of Pediatrics and Medicin
College of Medicine
Howard University
Washington, D. C. 20001

Eugene Stead
Professor of Medicine, Emeritus
Duke University
Durham, North Carolina 27706

DHEW ETHICAL ADVISORY BOARD

Alternate Listing

ETHICS AND MORALS

Albert Moraczewski, O.P.
President, Pope John XXIII Medical-
Moral Research and Education Center
1438 South Grand Boulevard
St. Louis, Missouri 63104

James Perman
The Free Synagogue of Westchester
500 North Columbus Avenue
Mount Vernon, New York 10552

William Francis May, Ph.D.
Professor and Chairman
Department of Religious Studies
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Bloomington, Indiana 47401

LAW

Samuel I. Schuman
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Law School
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Barbara Underwood
Professor of Law
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New Haven, Connecticut 06520

PUBLIC

Lillian H. Harvey
Dean, School of Nursing
Tuskegee Institute
Tuskegee, Alabama 36088

Mary Robinson
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and Child Center
3513 Dennlyn Road
Baltimore, Maryland 21215

BEHAVIORAL SCIENCES

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Department of Sociology
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San Francisco, California 94132

Gerald L. Klerman
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Massachusetts General Hospital
Fruit Street
Boston, Massachusetts 02114

David Mechanic, Ph.D.
Professor of Sociology and Director
Center for Medical Sociology and
Health Services Research
Department of Sociology
University of Wisconsin
Madison, Wisconsin 53706

BIOMEDICAL SCIENCES

Ben Miller Peckham
Chairman, Department of Obstetrics
and Gynecology
University of Wisconsin
Madison, Wisconsin 53706

Charles A. Alford, M.D.
Professor of Pediatrics
University of Alabama
School of Medicine
Birmingham, Alabama 35233

Marian L. Rivas
Associate Professor of Medical
Genetics
University of Oregon Health
Sciences Center
Portland, Oregon 97201

Lloyd H. Smith
Professor and Chairman
Department of Medicine
University of California
San Francisco, California 94102

5. The National Institutes of Health Guidelines on Recombinant Deoxyribonucleic Acid (DNA) Research

Issues:

(1) Extension of the NIH Guidelines to the public and private sectors, with a mechanism for monitoring compliance. (This would include the role of the Federal Interagency Committee--chaired by the Director, NIH--in these activities).

(2) Publication of the final NIH Environmental Impact Statement.

(3) Review of DHEW policy on the patenting of recombinant DNA research inventions developed under DHEW support.

Summary of Policy Actions:

(1) Federal Interagency Committee. By mid-March, the Committee should have recommendations for the President regarding legislative or executive actions necessary to ensure compliance with the standards set for this research. In light of a petition by the Environmental Defense Fund to the Department, the Center for Disease Control is being considered for possible "regulator" in necessary activities.

(2) Draft Environmental Impact Statement. Revision of the statement--to take into account public comments received--should be completed by mid-February, with publication of the final statement shortly thereafter.

(3) Patent Policy. An initial appraisal of all comments received by the NIH on DHEW patent policy suggests that recombinant DNA research inventions developed under DHEW-NIH support should be administered, as are

other research inventions, within current DHEW patent agreements with universities. However, it should be noted that Federal patent policies are under extensive review by the Executive Branch and the Congress. This may directly affect the Department's policies. Indeed, several members of the Congress have expressed concern on the patenting of recombinant DNA research inventions in light of the recently announced policy of the Patent Office in the Department of Commerce that patent claims for these inventions will receive expedited service. Further consultation with the Congress may be in order before the Department announces its position in this area.

Background: After extensive scientific and public review, the National Institutes of Health, on June 23, released guidelines that established strict conditions for the conduct of NIH-supported research on recombinant DNA molecules, which may be described as recombined segments of deoxyribonucleic acid (DNA), the material that determines the hereditary characteristics of all known cells. The NIH Guidelines establish carefully controlled conditions for the conduct of experiments involving the insertion of such recombinant genes into organisms such as bacteria. The Guidelines were published in the Federal Register on July 7 for public comment.

Environmental Impact Statement. The NIH undertook to prepare and filed a Draft Environmental Impact Statement in the Federal Register on September 9 and extended the period for public comment to December 15. The draft Statement is currently being revised to take into account issues raised by public commentators.

Department Patent Policy. In June, shortly before the release of

the Guidelines, Stanford University and the University of California asked NIH to review DHEW policies relating to the patenting of recombinant DNA research inventions developed under NIH grants or contracts. Under current DHEW patent regulations, invention rights to discoveries developed under the Department's research support are normally allocated in either of two ways:

o The Department may enter into an Institutional Patent Agreement (IPA) with a university or other nonprofit institution that has adequate mechanisms for administering patents on inventions. The IPA provides the institution the first option to own all inventions made in performance of Department grants or contracts, subject to a number of conditions deemed necessary to protect the public interest.

o For those institutions that have not entered into a patent agreement with the Department, determination of ownership is deferred until an invention has been made, at which time an institution may petition the Department for ownership of the invention.

The NIH solicited opinions from a number of different groups in the scientific community and the public and private sectors concerning those departmental patent policies, with respect to recombinant DNA research inventions. An analysis of the issues raised by the commentators is currently under way.

Published Proceedings. In August, the NIH also published a volume containing the transcript of an NIH public hearing held on the proposed Guidelines as well as the correspondence received by the Director, NIH, on this matter and relevant meetings held prior to the release of the Guidelines in June. A second volume is planned for publication in late spring

documenting the correspondence to the NIH on the Guidelines, the Impact Statement, and Departmental patent policy.

Federal Interagency Committee. In a letter to the President last summer, Senators Kennedy and Javits recommended executive action to extend the scope of the NIH Guidelines to the rest of the public and private sectors. In response, the President, at the suggestion of DHEW, recommended the creation of an interagency committee to review these and other important policy matters pertaining to recombinant DNA research. The Senate Health Subcommittee, under the chairmanship of Senator Kennedy, conducted oversight hearings on September 22 that focused on the need to extend the NIH Guidelines to the public and private sectors with a mechanism to ensure compliance. Dr. Fredrickson, the Director, NIH, testified that an interagency committee would review these matters and come forth with appropriate recommendations.

A memorandum was sent by the President on September 22 to all Government Department and agency heads requesting their cooperation in the formation of an interagency committee. Following that memorandum, Secretary of Health, Education, and Welfare David Mathews sent a letter to agency heads requesting that they nominate representatives to serve on this committee. Dr. Fredrickson is serving as chairman.

The mandate of the interagency committee is to review the nature and scope of Federal and private sector activities relating to recombinant DNA research, and to determine the applicability of the NIH Guidelines to govern this research in the public and private sectors. The committee will recommend whether legislative or executive action is necessary to ensure compliance to standards. Contacts have been made and are being pursued to

determine the scope of this activity and the application of NIH Guidelines to private industry.

All Federal research Departments and agencies have endorsed the NIH Guidelines and have agreed to share a registry documenting all federally supported or conducted recombinant DNA research. The general counsels of all regulatory agencies represented on the committee have completed a review of relevant authorities and have determined that no agency or Department has complete authority to govern the conduct of this research.

The committee is currently considering what steps might be appropriate for interim as well as long-term regulation of this research.

6. Study of Mission Boundaries of the Public Health Service

Issues: What would be an appropriate way to study mission boundary problems of the PHS?

NIH Recommendation:

A low-key, in-house study, sharply focused on easily identified "boundary problems," between and among PHS agencies, would make most sense. [This would be less disruptive and probably at least as useful as a more ambitious study, focused on possible shifts in basic agency missions].

Purpose of the Study: to identify those boundary problems (present or anticipated) that appear to be both significant and "actionable"; identify options for corrective actions (with pros and cons on each), plus recommended position.

Assign responsibility for the study to the Office of the Assistant Secretary for Health. A two-level study team is proposed: There would be a Policy Group, preferably consisting of the Assistant Secretary for Health, all PHS agency heads, and an appropriate representative from the Office of the Secretary. There would also be a "Working Group" to include one or more knowledgeable representatives from the senior staff of each PHS agency, OASH, and OS.

1/"Boundary problems" are of two kinds: Those arising from apparent gaps or overlaps in mission assignments; and those arising from the lack of effective mechanisms shared by two or more agencies, so that inter-related actions are not coordinated, needed communication does not occur, and the activities of the parts do not add up to a coherent health "system".

o The "Working Group" would be responsible for drafting the Study design (to include scope, proposed approach, resource needs and timing) for which approval of the Policy Group would have to be obtained.

o As inputs to study design proposals, each agency would be invited to identify boundary or related problems from its own perspective, and to indicate which were believed to warrant study; also to suggest study approaches.

o The Working Group would be expected to carry out (or oversee) the various elements of the study as finally agreed upon; then to draft the final report--to include recommendations for Executive or legislative action--again for review and concurrence by the Policy Group, and for submission to the Secretary for final approval.

[Note: Also needed is a comparable study of how health activities of the PHS agencies could be related more effectively to other health missions within the Department, such as Medicare and Medicaid].

Discussion:

In the past decade, there have been 5 major reorganizations of the PHS: in 1967, 1968, 1970, 1971, and 1973; also a study of PHS research components by the President's Biomedical Research Panel in 1975-76. [See the Attachment for a summary of recent organizational changes].

While a case probably could be made for yet another major reorganizational study, in the NIH view, a better case exists for tidying up the present structure. In this latter case, the changes sought would be the minimum to: (1) clarify specific agency responsibilities where overlapping or non-assigned functions diminish overall PHS effectiveness; and (2) to

establish or strengthen mechanisms for coordination and information exchange at the interface between the various PHS agencies, so that the PHS more closely approximates a coherent health "system."

Some of the functional areas in which assignments to PHS agencies aren't well spelled out include: responsibility for "control and demonstration" programs 2/; health education; "technology assessment"; clinical trials for validating new or existing health practices; high technology screening and testing related to health regulatory activities; health care standards setting;" etc.

In general, mechanisms for transferring new knowledge across the health research/health care interface are ineffective in most settings: they work rather well in medical center teaching hospitals, or comprehensive research/care disease centers, but not very well in ordinary community settings. [The NIH is exploring this particular problem from its own point of view, and will have recommendations shortly. But problems of this kind are not unique to this agency, and the matter should be a part of any serious study of the PHS].

2/ "Control and demonstration" now usually refers to the provision of special training and other resources needed for the adoption of relatively complex new diagnostic or therapeutic procedures (generally coming from research) in ordinary community health settings.

RECENT ORGANIZATIONAL CHANGES. The Public Health Service Act of July 1, 1944, brought together on an integrated basis the many authorities of the Service that had been enacted since 1798 and that had continuing utility. In some important particulars, authority that had been restricted was now extended. The Public Health Service Act of 1944 divided PHS into four bureaus: the Office of the Surgeon General; the National Institutes of Health; the Bureau of Medical Services; and the Bureau of State Services. In 1953, PHS, along with other units of the Federal Security Agency, became a component of the newly created Department of Health, Education, and Welfare. The basic structure of the Public Health Service remained the same until the 1960s.

In the early 1960s, unsuccessful attempts were made to modify the law to permit some modernization of the PHS structure. Finally, in 1966, President Lyndon B. Johnson sent to Congress his Reorganization Plan Number 3, which became effective in June of that year. This authority empowered the Secretary of HEW to reorganize the Public Health Service without formal approval of Congress. Anticipating this authority, DHEW Secretary John Gardner appointed, in the summer of 1965, an external ad hoc committee, chaired by Dr. John Corson of Princeton University, to make a detailed study of the Department's health functions.

Secretary Gardner established the new organization of PHS, effective January 1967, based on the committee's report. As reconstituted, the Service consisted of (1) five operating bureaus: the National Institutes of Health; the Bureau of Disease Prevention and Environment Control; the National Institute of Mental Health; the Bureau of Health Services; and the Bureau of Health Manpower; (2) two specialized activities: the National Center for Health Statistics and the National Library of Medicine; and (3) the Office of the Surgeon General. This structure became known as the "five-bureau" organization, but it was to be short-lived.

The Federal role in meeting the health problems of the Nation continued to undergo dramatic changes in size, scope, and nature throughout the 1960s in response to the evolving needs of society. President Johnson, in 1968, once again called upon the Secretary of DHEW to submit another organization plan to "achieve the most efficient and economic operation of the health programs of the Federal Government." As a result of this mandate, then Acting HEW Secretary Wilbur Cohen soon restructured the Public Health Service once more. The following changes in the PHS organization were made: (1) the Assistant Secretary for Health and Scientific Affairs was given line responsibility for the direction of PHS. The Office of the Surgeon General became greatly deemphasized although it retained authority for administration of the PHS Commissioned Corps. For the first time in American history, a noncareer official became the Federal Government's top health officer; (2) the Food and Drug Administration was transferred to the Public Health Service; (3) the National Institutes of Health were elevated to the status of an operating agency; and (4) a new operating agency, called the Health Services and Mental Health Administration, was created. The FDA Commissioner, the NIH Director, and the HSMHA Administrator were made responsible to the Assistant Secretary.

Added to NIH were the Bureau of Health Manpower and the National Library of Medicine, thereby bringing together the principal activities dealing with, and supporting, the medical schools and the universities. The newly created Health Services and Mental Health Administration (HSMHA) consisted of all that previously had been the Public Health Service, except NIH, the Bureau of Health Manpower, and the National Library of Medicine.

Later in 1968, DHEW Secretary Cohen, under a new reorganization order, created another agency of the Department of HEW—the Consumer Protection and Environmental Health Service (CPEHS). CPEHS was designed to include PHS activities on air pollution, urban and industrial health, and radiological health, all transferred from HSMHA—plus other activities of HSMHA's National Communicable Disease Center. Also included in this new CPEHS structure was the Food and Drug Administration. The rationale for this linking was that man's environmental milieu consisted of the products he consumed and used, as well as the elements of nature; therefore, it was felt that FDA and the environmental health aspects of DHEW should be brought together.

Reorganizing continued in PHS during the late 1960s and early 1970s as HSMHA underwent a number of internal reorganizations in 1968 and 1969. Then, in January 1970, DHEW Secretary Robert Finch announced that he was abolishing CPEHS and dividing it into two organizations, each at the level of an operating agency. Reestablished at that level was FDA, and a new unit, the Environmental Health Service. DHEW Secretary Finch felt that experience had shown little practical interaction between FDA and the remainder of CPEHS. Now the much restructured Public Health Service consisted of four operating agencies: HSMHA; NIH; FDA; and the new EHS. The Environmental Health Service, however, later was abolished when President Nixon created the

newly independent Environmental Protection Agency in late 1970. Nearly all of PHS' Environmental Health Service programs (including a program to combat water pollution) were transferred to EPA.

One major agency of HSMHA had been the National Institute of Mental Health. In May 1971, DHEW Secretary Elliot Richardson created a National Institute on Alcohol Abuse and Alcoholism as a component of NIMH. Concerning other facets of restructuring, substantial organizational and procedural changes resulted when extensive decentralization to the 10 Regional Health Directors took place in the early 1970s. Also, the title, Assistant Secretary for Health and Scientific Affairs, became Assistant Secretary for Health in November 1972.

CURRENT STRUCTURE

The most recent major reorganization of the Public Health Service took place in the summer of 1973. By 1972, HSMHA had become a rather unwieldy organization with 16 major components. A comprehensive study recommended a restructuring of the Public Health Service based upon the fact that PHS work in the health field seemed to center around five basic components: prevention; research; resource development; services; and compliance. A subsequent study concerning the important issues of alcoholism and mental health recognized the need to establish a particular emphasis in these areas.

DHEW Secretary Weinberger abolished HSMHA in the summer of 1973 and, in its place, created three separate line agencies: the Center for Disease Control; the Health Resources Administration; and the Health Services Administration. Thus, as of that time, the Public Health Service, newly emphasized as a major entity within DHEW, consisted of the Office of the Assistant Secretary for Health and five line agencies: (1) the Center for Disease Control; (2) the Health Resources Administration; (3) the Health Services Administration; (4) the Food and Drug Administration; and (5) the National Institutes of Health.

The last part of the current restructuring of PHS line agencies was completed in late 1973. As stated before, it had been determined that an increased emphasis on programs dealing with alcoholism and mental health was needed. Programs in these areas were currently operating in the National Institute of Mental Health, which had been transferred to NIH in the summer of 1973. Later that year, DHEW Secretary Weinberger placed drug abuse programs with alcoholism and mental health programs creating the sixth and, as of now, the latest major line agency in PHS—the Alcohol, Drug Abuse, and Mental Health Administration. This last restructuring brings us to the present.

7. Additional Topics on which to Brief the Secretary

Issue: On which additional issues (relevant to NIH programs and activities), would it be appropriate for the Secretary to receive oral or written briefing?

NIH Recommendations: Apart from topics on which information already has been provided, it might be helpful for the Secretary to know about the following:

o Results of HEW audits, and NIH efforts to enforce new accounting practices in the Universities

o NIH recommendations for more effective transfer of new clinically relevant information across the health research/health care interface

o The role of NCI and the National Cancer Program within the broader biomedical research community

o The study and recommendations of the President's Biomedical Research Panel

o Details on the "Omnibus" Bill on biomedical research for which NIH is providing technical assistance to Senator Kennedy's Health Subcommittee, in anticipation of oversight hearings. [This will touch upon a wide range of legislative issues]

o The recent major NIH study of the NIH Peer Review System (including probable impact)

o Freedom of information/confidentiality problems (impact on peer review and on disclosure of preliminary scientific and clinical trial data)

o Unresolved policy issues in NIH support of research training

o Relationship of NIH to regulatory agencies (i.e., requests for assistance; impact of regulatory actions on NIH programs and grantee institutions).

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